

RECEIVED
AUG 07 2008
U.S. Patent and Trademark Office

IN THE CLAIMS:

Please amend Claim 1 as follows:

1 (Amended). A method for inhibiting the action of TNF for treating neurological conditions in a human by administering a TNF antagonist for reducing the inflammation of neuronal tissue or the neuromuscular junction of said human, or for modulating the immune response affecting neuronal tissue or the neuromuscular junction of said human, comprising the step of:

a) administering a therapeutically effective dosage level to said human of said TNF antagonist selected from the group consisting of etanercept, infliximab, pegylated soluble TNF receptor Type I (PEGsTNF-R1), other agents containing soluble TNF receptors, CDP571 (a humanized monoclonal anti-TNF-alpha antibody), other monoclonal anti-TNF-alpha antibodies, [TNF - alpha converting enzyme inhibitors] and D2E7 (a human anti-TNF mAb) for reducing the inflammation of neuronal tissue or the neuromuscular junction of said human, or for modulating the immune response affecting neuronal tissue or the neuromuscular junction of said human.

REMARKS

Applicant affirms its election of Claims 1 to 29, and applicant has cancelled non-elected Claims 30 to 99. Applicant is filing a divisional application for these Claims.

Applicant also has submitted a terminal disclaimer to overcome the double patenting rejection of Claims 1 to 29.

A new Declaration is submitted herewith.

The rejection of Claims 1 to 29 under 35 U.S.C. §103 as being unpatentable over the '272 patent to Le or the '481 patent to Levin, alone or in view of the '690 patent to Jacobs is respectfully traversed.

The Examiner refers to Le, col. 6, lines 26 to 39. However, Le does not teach that the specific TNF antagonists claimed by applicant in Claim 1 can be used to treat neurological conditions. That is, Le makes no teaching that etanercept, infliximab, pegylated soluble TNF receptor Type I (PEGs TNF-R1), other agents containing soluble TNF receptors, CDP571, other monoclonal anti-TNF-alpha antibodies and D2E7 can be used to treat neurological conditions.

Moreover, each of the TNF molecules recited in Claim 1 is chemically distinct. Etanercept, for example, is a fusion protein consisting of two TNF alpha receptors fused to the Fc portion of an immunoglobulin molecule. Infliximab is not a fusion protein; rather it is a chimeric antibody, having both human and mouse portions. D2E7 is a fully humanized antibody, having no mouse portions. Function is dependent upon structure; therefore, since the structure of these different molecules is so different, their functions are different. These TNF molecules have all been developed to treat arthritis. None have been aimed at neurological disorders. It is certainly not obvious that TNF molecules with such diverse and distinct structures will be effective for treating these neurological disorders which are so different from arthritis.

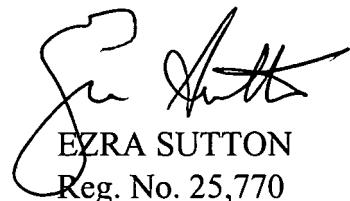
With regard to Levin, applicant has amended Claim 1 to delete "TNF-alpha converting enzyme inhibitors" (TACE). Therefore, this reference is no longer applicable to Claims 1 to 29.

With regard to Jacobs, it makes no teaching of using any of applicant's claimed TNF antagonists for treating neurological disorders. It addresses diseases such as arthritis. Further, there is no teaching in the prior art that "TNF antagonists in general are known to be effective at treating various neurological conditions" as stated by the Examiner. Applicant's own earlier patent (U.S. Patent No. 6,015,557) teaches the use of only 2 TNF antagonists, not TNF antagonists in general. In any event, applicant claims priority to U.S. Patent No. 6,015,557.

With regard to Claim 2, none of the prior art teaches applicant's forms of administration including intrathecal or intracerebroventricular administration. In addition, Claims 23 and 24 are directed specifically to administering etanercept and infliximab intrathecally at particular dosage levels. Further, Claims 28 and 29 are directed specifically to administering etanercept and infliximab intracerebroventricularly at particular dosage levels. None of the cited prior art references teach these specifically claimed features of applicant's Claims.

For these reasons, it is submitted that applicant's claims 1 to 29, as amended, patently distinguish over the prior art and should be allowed.

Respectfully submitted,



EZRA SUTTON
Reg. No. 25,770

Plaza 9, 900 Route 9
Woodbridge, New Jersey 07095
(732) 634-3520

ES/et